



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,855	11/13/2000	Brit Kalatz	RDID0006US	8566

32842 7590 09/11/2003

THE LAW OFFICE OF JILL L. WOODBURN, L.L.C.
JILL L. WOODBURN
128 SHORE DR.
OGDEN DUNES, IN 46368

EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 09/11/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/711,855

Applicant(s)

KALATZ ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 32, 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16 & 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments in Paper No. 18, filed July 24, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The new abstract has been accepted.
3. Claims 1-10, 12, and 32-37 are examined on the merits.

NEW CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

1. Claims 3, 5, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
2. This new matter rejection is necessitated by Applicants amendments.
3. Specific to claim 3, line 2, the limitation of "F is 0.25 mmol/l/g" is considered to be new matter. It is noted that the instant specification does not specify, "F is 0.25 mmol/l/g"; however, the instant specification discloses that "F is close to 0.25 mmol/l/g" (page 11, line 17) which is different from said limitation of claim 3.
4. Specific to claims 5, line 2 and 32, line 2, the limitation of "X, as the addend, is equal to SG(A)" is considered to be new matter. It is noted the instant specification discloses "the

Art Unit: 1631

variable X can contain the variable SG *A as the addend, which is different from the limitation of “X, as the addend, is equal to SG(A).”

CLAIM REJECTIONS - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2-5, 12, 32, 34, and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

3. This rejection is maintained with respect to claims 2-5, 12, 32, 34, and 35, as recited in the previous office action Paper No. 15, mailed February 24, 2003.

4. Specific to claim 2, the factor “E” is a non-enabled value due to R_{KH} not being enabled because it is not directly or indirectly defined in the specification as originally filed. It is acknowledged that the specification discloses that “E” is an empirical factor (Page 12, line 24) and “it is favorable to use $R_{KH} * F$ as E” (Page 11, lines 16-18). Applicants argue by pointed to support (page 11, lines 14-19) stating that the specification teaches that the factor “E” relates to the proportionality of the increase in the actual glucose value to the effective carbohydrate units in a projection period. Further, Applicants argue via Walsh et al. actual glucose values and effective carbohydrate units can be obtained without undue experimentation. Applicants’ argument and pointed to support have been considered, however, they have been found to be unpersuasive because the disclosure of “this proportionality is taken into account with the factor

Art Unit: 1631

E” with the above citation does not provide adequate guidance to one of skill in the art to practice the invention without undue experimentation.

5. The pointed to support does not provide sufficient guidance for one skilled in the art to derive either “E” or “ R_{KH} ” because the specification uses one undefined term such as R_{KH} to define another undefined term such as “E”. Therefore, it would require undue experimentation for one skilled in the art to derive these factors. Further, Applicants argue that the specification teaches in page 11 lines 14-19, that E is a factor that is related to the anticipated rise in glucose concentration due to the consumption of carbohydrates. The Examiner has not been able to find in the pointed to support wherein “E” is defined as stated above. However, the specific pointed to section discloses that “[t]his formula uses the factor KH_j to take into account the consumption of carbohydrates at numerous points in time, as well as the quantity of carbohydrate units consumed each time.” Further, the argument that “E” is related to another value such as the anticipated rise in glucose concentration is not persuasive because the definition of “E” relative to another value does not help one of skill in the art to derive the value “E.” One of skill in the art would still require adequate guidance beyond stating that “E” is related to another value for determining the value “E” without undue experimentation.

6. Specific to claim 3, the factor “ R_{KH} ” is a non-enabled value due to the lack disclosure of guidance of how one skilled in the art would derive the value R_{KH} . Applicants argue that R_{KH} could be assessed by back calculating from “E” (backwards from E). The argument has been found to be unpersuasive because the specification as originally filed does not provide adequate disclosure that would enable one skilled in the art to derive the value “E”; therefore, R_{KH} is not enabled due to “E” being not enabled as discussed above. Therefore, the specification does not

Art Unit: 1631

provide sufficient guidance for one skilled in the art to predictably derive the R_{KH} value for this particular model without undue experimentation.

7. Specific to claim 3, the factor “(F)” is a non-enabled value due to the lack of disclosure of guidance of how one skilled in the art would derive the value “(F)”. Applicants’ argument by amendment has been found to be unpersuasive due to the specification does not disclose “F” is 0.25 mmol/l/g (See the new matter rejection above). It is noted that the instant specification discloses factor “F” is close to 0.25 mmol/l/g . Therefore, it is re-iterated the specification does not provide sufficient guidance for one skilled in the art to derive the (F) value for this particular model without undue experimentation.

8. Specific to claims 12 and 35, the value “m” is a non-enabled value due to the lack of disclosure of guidance of how one skilled in the art would derive the value “m”. Applicants’ argument and pointed to support, Page 8, formula (4), have been found to be unpersuasive. The pointed to support as originally filed does not disclose sufficient guidance and direction for one skilled in the art to derive or conclude that “m” is an integer referring to the last consumption of carbohydrate that is taken into account. Applicants argue “this way of indicating a summation of summation factors is common in mathematics.” Applicants’ argument has been considered and found to be unpersuasive. It is noted that it is well known in the art to use a variable to represent an integer value within an equation for summation. It is further noted it is well known in the art that all variables are specifically defined as to what they represent for the summation calculation. Specific to this instant application, the variable “m” is not defined; therefore, it is not enabled. As originally filed, the variable “m” could symbolize just about anything that is related to a carbohydrate(s) in equation (4). Does “m” represent the number of carbons, hydrogen or oxygen

Art Unit: 1631

in a carbohydrate? Or does “m” represent a value of the different saccharide units contained within a carbohydrate? The specification does not provide sufficient guidance for one skilled in the art to derive the value “m” without undue experimentation.

9. Applicants argue that a skilled artisan would make an assumption that m is the number of the carbohydrate consumptions from comparing claims 11 and 12. It is noted that claim 11 has been cancelled (Paper No. 3, April 18, 2001); therefore, Applicants’ argument by reference to cancelled claim 11 is moot.

10. Applicants argue that “the specification is not required to teach every detail of the invention or to be a production specification”. Applicants’ argument has been found to unpersuasive. It is required that the specification disclose sufficient essential details that one skilled in the art would be enabled to make and use the claimed invention of the particular application or patent. The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.

CLAIM REJECTIONS - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1631

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 6-10, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington et al. (US005822715A) taken with Goldman et al. (US005542420A) in view of Conn et al. (WO 00/47109).

14. This rejection is maintained with respect to Claims 1, 6-10, 36, and 37, as recited in the previous office action Paper No. 15, mailed February 24, 2003.

15. The amendments to the claims under examination have been acknowledged.

16. Applicants' argue that Worthington et al. does not disclose a system wherein the "portion" of insulin dose or carbohydrates consumed is determined. Applicant's argument has been fully considered and found to be unpersuasive due to the instant application does not specify the "portion" of insulin dose or carbohydrates consumed in the specification or claim limitations. It is acknowledged that claim 1 recites the limitations of "portion" of insulin and carbohydrates; however, claim 1 does not specifically define the size of the "portion" of either insulin or carbohydrates. Therefore, the disclosure of Worthington et al., which is consistent

Art Unit: 1631

with the scope of the instant claim 1, has the limitation of determining an undefined “portion” of either insulin or carbohydrates.

17. Applicants argue that neither references of Goldman et al. or Conn et al. alone or in combination suggest the modification of Worthington et al. to meet the limitation of claim 1. Applicants’ argument has been fully considered and found to be unpersuasive as discussed below.

18. It is re-iterated Worthington et al. demonstrates a “diabetes management system” (abstract) that includes an apparatus, method and system that determines a predicted value of blood glucose concentrations at specific times as recited in claim 1. The teachings of Worthington et al. as applied to claims 1, 7-10, 36 and 37 are cited in Paper No. 11, mailed June 25, 2002, pages 4-5. However, Worthington et al. does not teach “the consumption of carbohydrates at numerous points in time” or “a memory unit for storing...carbohydrates consumed and their times of consumption.” Goldman et al. teaches “the system of the present invention which integrates the technological capabilities of current communication and data processing techniques with accumulation and storage of medical and health-related knowledge relating to individuals. Using various apparatus, including telephonic terminals, such knowledge may be accumulated over time, from multiple and varied sources, such as doctors, hospitals, medical laboratories, pharmacies, dieticians, as well as individual patients themselves” (Column 3, lines 27-35). “To consider an exemplary application, after the basic health and environmental information has been stored for a subject’s, edible-consumption information is supplied by the individual, typically on-line, at the time of consumption. Again, using the data input as represented by block 12, the individual's eating habits and drug intake are specified and stored.

Art Unit: 1631

Information from the data input block 12 in the form of a personal health profile is supplied to an evaluation block 14 that also receives pertinent data regarding human needs stored as indicated by an edible-needs block 16. The evaluation block 14 processes the personalized and generic data to arrive at recommended intake quantities (RIQ) for an individual subject. That is, the individual's requirements are defined preliminarily setting forth the various edibles including drugs, vitamins, antioxidants, minerals, proteins, fats, carbohydrates and so on for the specific individual" (Column 6, lines 34-51). Further, Worthington et al. does not teach the device to be a microdialysis device for determining actual glucose concentrations. Conn et al. teaches a system made up of devices and methods to determine the "concentration of an analyte present in a biological system" (Abstract) as applied to glucose monitoring in diabetic patients. Conn et al. teaches a sensing mechanism or device that performs microdialysis (Page 2, line 15) to determine actual glucose concentration in a sample from "across a skin or mucosal surface" (Page 2, line 2).

19. It is noted that Conn et al. discloses the concept of an automatic approach to improving the quality of life for people with diabetes (treatment) (page 1, lines 12-17) and Goldman et al. discloses a system for treating patient with extreme conditions such as diabetes (column 12, lines 51-56). While, Worthington et al. discloses a system for treating patients with diabetes (Abstract etc.). Therefore, Conn et al. and Goldman et al. suggest the concept of improving the quality of life for patient with diabetes, which is directly applicable to the system of Worthington et al. for treating patients with diabetes.

20. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to practice the diabetes management system of Worthington et al. One of

Art Unit: 1631

ordinary skill in the art at the time of the invention would have been motivated by the teachings of Goldman et al. to personalize the system of Worthington et al. by integrating the technological capabilities of current communication and data processing techniques with accumulation and storage of medical and health-related knowledge relating to individuals (Column 3, lines 27-30). Further, one of ordinary skill in the art at the time of the invention would have been motivated by the teachings of Conn et al. to modify the monitoring device of Worthington et al. and Goldman et al. to perform microdialysis to determine glucose concentrations. Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to personalize the monitoring system of Worthington et al. as taught by Goldman et al. (Abstract) and further, motivated by the need to perform microdialysis to determine glucose concentrations and self-monitoring of blood glucose levels with a "painless and automatic approach" as taught by Conn et al. (Page 1, lines 12-16).

CONCLUSION

21. CLAIM 33 IS ALLOWED.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1631

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

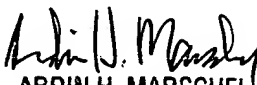
24. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

27. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
9/10/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER